SEP 2 3 2003

K 031305 1/2

510(k) SUMMARY
Olympus Ultrasonic Surgical System

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR, Section 807.92.

A. General Information

1. Applicant

Aomori Olympus Co,. Ltd.
2-248-1, Okkonoki
Kuroishi-shi, Aomori-ken,
036-0357 Japan
(Registration No.: 9614641)

2. Submission Correspondent

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Olympus Optical Co., Ltd.
2951 Ishikawa-cho, Hachioji-shi,
Tokyo 192-8507, Japan
TEL: 81-426-42-2891
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(Registration No.: 8010047)

3. Official Correspondent

Tina Steffanie-Oak
Senior R.A. Analyst
Olympus America Inc.
Two Corporate Center Drive, Melville,
NY 11747-3157
TEL: 631-844-5477
FAX: 631-844-5554
E-mail: Tina.Steffanie-Oak@olympus.com
(Registration No.: 2429304)

B. Device Name, Common Name

1. **Device Name** : Olympus Ultrasonic Surgical System
2. **Common/Usual Name** : Ultrasonic Surgical System
3. **Classification Name** : Class II Instrument, Ultrasonic Surgical LFL

C. Predicate Devices :

#K012176 Harmonic Scalpel
#K972114 Olympus SonoSurg Scissors Set T3000
#K972114 Olympus Transducer MAJ-336
#K000095 SonoSurg Generator Set SonoSurg-G2 Set

D. Summary Description of the Device

1. Summary

The Olympus Ultrasonic Surgical System is composed of three sections, (1), (2), and (3).

(1) Olympus SonoSurg Scissors 5mm O.D. T3050" or "Olympus SonoSurg Long Hook 5mm O.D. T3060" or "Olympus SonoSurg Long Scissors 5mm O.D. T3070", or "Olympus SonoSurg Scissors 5mm O.D., HF Series.
(2) Olympus SonoSurg Transducer SonoSurg-T2H.
(3) Olympus SonoSurg Generator Set SonoSurg-G2 Set (SonoSurg-G2, MAJ-51).

This device is intended to cut and coagulate soft tissue for open and endoscopic procedures in ENT(Ears, Nose, Throat) surgery.

2. Design

"Olympus Ultrasonic Surgical System" has been designed, manufactured and tested in compliance with Voluntary Safety Standards. It meets the requirements of IEC 60601-1, IEC60601-1-1,IEC60601-1-2.

3. Materials

There are no new patient-contacting materials.

E. Intended Use of the device

Olympus Ultrasonic Surgical System has been designed to be used with the Olympus SonoSurg Generator Set (SonoSurg-G2 Set) and an electrosurgical unit to cut and coagulate soft tissue for laparoscopic and intraabdominal procedures in general(open) surgery. Also it has been designed to be used with them to cut and coagulate soft tissue for open and endoscopic procedures in ENT(Ears, Nose, Throat) surgery.

F. Technological Characteristics

Theory of the operation of "Olympus Ultrasonic Surgical System" is that the electrical energy employed in the "Olympus SonoSurg-G2" is changed to mechanical energy by ultrasonic vibration in the "Olympus SonoSurg Transducer SonoSurg-T2H". Therefore, this system can cut and coagulate body tissue by ultrasonic vibration. This system is the same as the Predicate Devices which include, "Olympus SonoSurg Scissors Set T3000(#K972114)", "Olympus Transducer MAJ-336 (#K972114)" and "Olympus SonSurg-G2 (#K000095)".

G. Reason for not requiring clinical data

When compared to the predicate devices, "Olympus Ultrasonic Surgical System" does not incorporate any significant changes that would effect safety or efficacy. Therefore clinical data is not necessary for its evaluation of safety.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 23 2003

Olympus Optical Co., Ltd
c/o Ms. Tina Steffanie-Oak
Senior R.A. Analyst
Olympus America, Inc.
Two Corporate Center Drive
Melville, New York 11747-3157

Re: K031305
Trade/Device Name: Olympus Ultrasonic Surgical System
Regulatory Class: Unclassified
Product Code: LFL
Dated: July 25, 2003
Received: July 29, 2003

Dear Ms. Steffanie-Oak:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

OLYMPUS

Indications for Use Statement

510(k) Number(if known): Not assigned yet. K031305
Device Name: Olympus Ultrasonic Surgical System

Indications for Use :

OLYMPUS Ultrasonic Surgical System has been designed to be used with the Olympus SonoSurg generator Set (SonoSurg-G2 Set) and an electrosurgical unit to cut and coagulate soft tissue for laparoscopic and intrabdominal procedures in general (open) surgery. Also it has been designed to be used with them to cut and coagulate soft tissue for open and endoscopic procedures in ENT(Ears, Nose, Throat) surgery.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use
(Prescription 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K031305